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Amendment and Response

Scrial No.: 09/529,691 Confirmation No.: 3203 Filed: August 29, 2000

For: INHIBITION OF TUMOR CELL ADHESION TYPE IV COLLAGEN

Remarks

The Office Action mailed January 2, 2002 has been received and reviewed.

Claims 4-8 and 14-18 having been amended, and claims 1-3 and 9-13 having been cancelled, and claims 22-32 having been added, the pending claims are claims 4-8 and 14-32. Reconsideration and withdrawal of the rejections are respectfully requested.

The new and amended claims are fully supported by the originally filed claims and the specification. For example, the sequence in claim 22 is supported by the specification at page 5, lines 29-30. The language regarding the non-peptide moieties in claim 32 is supported by the specification at page 7, lines 22-35 and page 9, line 57. No new matter has been added.

It is respectfully submitted that the new claims be considered as they do not require a significant amount of additional work on the part of the Examiner.

Obviousness-Type Double Patenting Rejection

Claims 1-21 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 5,082,926-A (Chelberg et al.). This rejection is respectfully traversed as the claims of U.S. Patent No. 5,082,926 do not teach or suggest any peptides or peptide conjugates in the all D-form or in the all L-form when bound to specific non-peptide moieties. Upon an indication of otherwise allowable subject matter and in the event this rejection is maintained, Applicants will provide an appropriate response.

Interview Summary Record

Applicants' Representatives thank the Examiner for the courtesy extended in the interview on April 16, 2002. The substance of the interview included a discussion of the amendments and claims presented herein.

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The 35 U.S.C. §112, First Paragraph, Rejection

The Examiner rejected claims 6-8 and 16-21 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is respectfully traversed in view of the presently pending claims.

The Examiner rejected claims 1-21 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is respectfully traversed in view of the presently pending claims.

The 35 U.S.C. §112, Second Paragraph, Rejection

The Examiner rejected claims 2-4, 12-14, and 16-21 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. This rejection is respectfully traversed in view of the presently pending claims.

The 35 U.S.C. §102 Rejection

The Examiner rejected claims 1-4 and 6-8 under 35 U.S.C. §102(b) as being anticipated by Knutson et al. (*Proceedings of the American Association for Cancer Research*, 36:68, Abstract No. 407, 1995). This rejection is respectfully traversed. There is no specific teaching or suggestion of the currently pending claims. That is, there is no enabling disclosure that would lead one to Applicants' specific claims. For example, there is no disclosure of conjugated peptides as claimed, there is no disclosure of methods of use of peptides or conjugated peptides as claimed, and there is no disclosure of the peptides as claimed.

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The Examiner rejected claims 1-15 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,082,926-A (Chelberg et al.). This rejection is respectfully traversed. There is no specific teaching or suggestion of the currently pending claims. That is, there is no disclosure that would lead one to Applicants' specific claims. For example, there is no disclosure of conjugated peptides as claimed, there is no disclosure of methods of use of peptides or conjugated peptides as claimed, and there is no specific disclosure of all-D forms of any peptides.

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Summary

It is respectfully submitted that the pending claims 4-8 and 14-32 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

> Respectfully submitted for FIELDS et al.

By

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CERTIFICATE UNDER 37 C.F.R. §1.8: The undersigned hereby certifies that this Facsimile Cover Sheet and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office addressed to Assistant Commissioner for Patents, Washington, D.C. 20231, on this day of May, 2002, at 4,00 pm (Central Time).

lay 2, 2002

May 2, 2002

Signature: Se Donbroske

APPENDIX A - SPECIFICATION/CLAIM AMENDMENTS INCLUDING NOTATIONS TO INDICATE CHANGES MADE

Serial No.: 09/529,691 Docket No.: 110.01680101

Amendments to the following are indicated by underlining what has been added and bracketing what has been deleted. Additionally, all amendments have been shaded.

In the Claims

For convenience, all pending claims are shown below.

- 4. (Amended) [The] A polypeptide [of claim 3] having the sequence gly-val-lys-gly-asp-lys-gly-asn-pro-gly-trp-pro-gly-ala-pro. which is in the all D-form.
- 5. (Amended) The polypeptide of claim [4] 4 further comprising a cytotoxic agent covalently bonded thereto.
- 6. (Amended) The polypeptide of claim [1] 4 which inhibits binding of tumor cells to type IV collagen.
- 7. (Amended) The polypeptide of claim [1] 4 which inhibits tumor cell invasion into basement membranes.
- 8. (Amended) The polypeptide of claim [4] 4 which inhibits tumor cell metastasis.
- 14. (Amended) [The] A peptide-conjugate [of-claim 13] comprising a polypeptide having the sequence gly-val-lys-gly-asp-lys-gly-asn-pro-gly-trp-pro-gly-ala-prowhich is in the all D-form; wherein the polypeptide is bonded to a non-peptide moiety.
- 15. (Amended) The peptide-conjugate of claim [9] 14 further comprising a cytotoxic agent covalently bonded thereto.

Amendment and Response - Appendix A

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Applicant(s): FIELDS et al. Serial No.: 09/529,691 Filed: August 29, 2000

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- 16. (Amended) A method of inhibiting tumor cell binding to type IV collagen comprising contacting the tumor cell with a polypeptide of claim [2] 4 or a peptide-conjugate of claim [9] 14.
- 17. (Amended) A method of inhibiting tumor cell invasion of a basement membrane comprising modulating the tumor cell with a polypeptide of claim [4] 4 or a peptide-conjugate of claim [9] 14.
- 18. (Amended) A method of inhibiting tumor cell metastasis comprising modulating the tumor cell with a polypeptide of claim [4] 4 or a peptide-conjugate of claim [9] 44.
- 19. The method of claim 16 which is carried out in vivo.
- 20. The method of claim 17 which is carried out in vivo.
- 21. The method of claim 18 which is carried out in vivo.
- 22. (New) A polypeptide having the sequence pro-ala-gly-pro-up-gly-pro-asn-gly-lys-asp-gly-lys-val-gly, which is in the all D-form.
- 23: (New) The polypeptide of claim 22 further comprising a cytotoxic agent covalently bonded thereto.
- 24. (New) the polypeptide of claim 22 which inhibits binding of tumor cells to type IV collagen.
- 25. (New) The polypeptide of claim 22 which inhibits tumor cell invasion into basement membranes.

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Amendment and Response - Appendix A

Applicant(s): FIELDS et al. Serial No.: 09/529,691 Filed: August 29, 2000

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- 26 (New) The polypeptide of claim-22 which inhibits tumor cell metastatis:
- (New). A peptide-conjugate comprising a polypeptide pro-ala-gly-pro-up-gly-pro-asn-gly-lys-asp-gly-lys-val-gly, which is in the all D-form, wherein the polypeptide is bonded to a non-peptide moiety.
- 28: (New): The peptide-conjugate of claim 27 further comprising a cytotoxic agent covalently bonded thereto.
- 29. (New) A method of inhibiting tumor cell binding to type IV collagen comprising contacting the tumor cell with a polypeptide of claim 22 or a peptide-conjugate of claim 27.
- (New). A method of inhibiting tumor cell invasion of a basement membrane comprising modulating the tumor cell with a polypeptide of claim 22 or a peptide-conjugate of claim 27.
- (New) A method of inhibiting tumor cell metastatis comprising modulating the tumor cell with a polypeptide of claim 22 or a peptide conjugate of claim 27.
- 32. (New) A peptide-conjugate comprising a polypeptide having the sequence gly-val-lysgly-asp-lys-gly-asn-pro-gly-trp-pro-gly-ala-pro, which is in the all L-form, wherein the
 polypeptide is bonded to a non-peptide moiety selected from the group consisting of an
 organic group having an alkyl chain, a phospholipid a polyalkylene glycol; a DNA
 intercalator, a metal chelator, an alkylating agent, and a membrane-disrupting agent.